UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

February 13, 2023

John D. Abbott, Ph.D.
North America Head Regulatory & Stewardship
Syngenta Crop Protection, LLC
P.O. Box 18300
Greensboro, NC 27419-8300

Subject: Agency Response to Letters Dated June 15, 2021, and January 26, 2023, Concerning Data Compensation

Dear Dr. Abbott:

The Agency is responding to your letters dated June 15, 2021, and January 26, 2023, concerning certain registrants that you discovered had submitted applications certifying that sources of active ingredients were purchased from Syngenta Crop Protection (Syngenta). Your letters indicate that Syngenta neither supplies nor intends to supply these companies (or any companies without Syngenta's written confirmation) with its active ingredients or end use products.

EPA does not interpret FIFRA Section 3(c)(2)(D) as allowing an applicant to certify formulation using another company's registered product while submitting data developed using an unregistered source. In general, the Registration Division (RD) will continue its policy of registering products that claim the Formulator's Exemption, taking the certification therein at face value, without requiring an accompanying proof of purchase. However, as indicated in the Agency memo dated January 14, 2021, if RD has reason to believe that a basic manufacturer has no intention of selling its product to a particular applicant, RD will on a case-by-case basis continue to request evidence indicating that the basic manufacturer does not object to the secondary applicant identifying the basic manufacturer's product(s) as the source of the product(s) or active ingredients identified in the applied-for product. As requested, RD will follow this process for pending applications submitted by companies provided in your letter that list Syngenta active ingredients on their Formulator's Exemption forms. This process has already begun and will continue as needed.

In addition, EPA has requested, and will continue to request, that applicants immediately withdraw pending applications that are supported by product chemistry and/or acute toxicity data generated using an active ingredient source not listed on the originally submitted CSF. This Agency practice has resulted in the recent withdrawal of several registration actions submitted under the Formulators' Exemption.

Finally, if an applicant is using the cite-all method and/or selective citation method to address the generic data requirements for new actions, and the Agency believes that the applicant may not have made offers to pay to all relevant data submitters, RD, on a case-by-case basis, may request that the applicant provide offer to pay letters with proof that the letters were sent to the data submitters. Where applications cite exclusive use studies, a Letter of Authorization from the data submitter must be provided.

If you have any questions regarding this letter, please contact me 202-566-2875 or at rosenblatt.dan@epa.gov.

Respectfully,

DANIEL ROSENBLATT

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Daniel Rosenblatt, Acting Director
Registration Division
Office of Pesticide Programs
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202-566-2875